DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 8 2009

Re: Letairis
Docket Nos.: FDA-2008-E-0113
FDA-2008-E-0114
FDA-2008-E-0103
FDA-2008-E-0110

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,703,017; 5,840,722; 5,932,730; and 7,109,205, filed by Abbott Gmbh & Co., KG, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Letairis (ambrisentan), the human drug product claimed by the patents.

The total length of the regulatory review period for Letairis (ambrisentan) is 1,871 days. Of this time, 1,691 days occurred during the testing phase and 180 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 3, 2002.

   The applicant claims July 4, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 3, 2002, the date a previous IND was removed from full clinical hold.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 18, 2006.

   FDA has verified the applicant's claim that the new drug application (NDA) for Letairis (ambrisentan) (NDA 22-081) was initially submitted on December 18, 2006.

3. The date the application was approved: June 15, 2007.

FDA has verified the applicant's claim that NDA 22-081 was approved on June 15, 2007.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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